Maryland
DEPARTMENT OF HEALTH

PRESCRIBER'S STATEMENT OF MEDICAL NECESSITY
Prior-Authorization for payment of Orfadin™ (nitisinone or NTBC)
Maryland Pharmacy Program

Tel#: 1-800-492-5231 Option 3-Fax form to: 410-333-5398

(**Incomplete forms will be returned**)

Patient Information

Patient location:____home;_____hospital____Clinic___Office DOB: _____
Patient Name:_____
MA ID#:_____ Adddress: _____
Tel.#:(_____)_____-_____ _____

Prescriber Information

Is Drug prescribed as part of a clinical study? ☐ Yes ☐ No
Specify sponsoring organization/drug manufacturer_____
List study drug:_____. Specify purpose of study: _____
Note: For the Program to approve off-label use or use of the drug at dosages other than recommended by FDA, such use must be medically necessary and be documented in one of the three official compendia (the American Hospital Formulary Service Drug Information, the Micromedex/Drugdex drug database and the U.S. Pharmacopeia.

I certify that Patient is **not** enrolled in any study involving the requested drug. I will be supervising the patient's treatment accordingly. Supporting medical documentation is kept on file in the patient's medical record.

_____, M.D. Prescriber's Name:_____Date: _____
(Prescriber's signature). Tel# (_____) –_____-_____Fax# (_____) -_____- _____
License #:_____DEA #:_____Specialty : _____
Consultations with: ☐ Biochemical geneticist- ☐ Hepatologist/gastroenterologist - ☐ Hematologist- ☐ Other:_____
Address: _____

Prescription/Clinical Information

Drug/strength prescribed:_____Dosage/ dosage frequency:_____
(Adult dose: 1mg/kg/day divided bid at least 1 hr ac initially; not to exceed 2mg/kg/day;
Pediatric dose: 1mg/kg/day divided bid at least 1 hr ac initially; may increase to 1.5mg/kg/day after 1 month if biochemical parameters not normalized, not to exceed 2mg/kg/day)
List diagnosis for which the drug was prescribed:
☐ Transient tyrosinemia of the newborn (TTN)
☐ Tyrosinemia II (Richner-Hanhart syndrome)
☐ Tyrosinemia III
☐ Type I hereditary tyrosenemia (hereditary infantile tyrosinemia)- Homozygous form? ☐ Yes ☐ No Gene mapped to band 15q23-q25? ☐ Yes ☐ No ☐ Chronic form ☐ Acute form
☐ Other: _____
Is patient currently placed on a liver transplantation waiting list? ☐ Yes ☐ No
Will Patient likely become a candidate for liver transplantation within the next year? ☐ Yes ☐ No
Is patient under a care of a skilled nutritionist and on diet restricted in tyrosine and phenylalanine? ☐ Yes ☐ No
Are the dietary restrictions of tyrosine and phenylalanine alone sufficient to maintain the urinary succinylacetone at or below detectable levels? ☐ Yes ☐ No Patient's Current Weight:_____lb or_____kg
Urinary succinylacetone level:_____
Plasma tyrosine level:_____umol/L Normal range:_____Test Date:_____/_____/____
Serum alpha-fetoprotein concentration:_____Normal range:___Test Date:_____/_____/__ Serum phospate level:_____Normal range:_____ Test Date:_____/_____/__ Blood count, thrombocytes, leukocytes? ☐ Normal ☐Abnormal range- Date of last blood test measurement:/_____/____
Normal slit lamp examination prior to therapy/post-therapy? ☐ Yes ☐ No Date of last exam:_____/_____/_____
A copy of Patient's Medical History must accompany this request.

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